

**OCCLUDING VASCULATURE OF A PATIENT
USING EMBOLIC COIL WITH IMPROVED PLATELET ADHESION**

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FIELD OF THE INVENTION

The present invention concerns a novel method for occluding the vasculature of a patient and, more particularly, a method of treatment in which embolic coils are placed within the patient's vasculature.

BACKGROUND OF THE INVENTION

A known technique for treating a brain aneurysm of a patient includes the placement of embolic coils within the aneurysm. To this end, a catheter is introduced into the vessel leading to the aneurysm, and embolic coils are delivered to pack and fill the aneurysm. Ordinarily, a deployment system is used to deliver the coils, via the catheter, to the aneurysm, such as the deployment system disclosed in Hieshima U.S. Patent No. 6,113,622, the disclosure of which is incorporated herein by reference.

The embolic coils act to reduce the blood flow inside of the aneurysm. Typically the embolic coils provide a mechanical blockage to the blood flow in the aneurysm. In this manner, the stagnation of blood that is obtained prevents the blood flow from rupturing the aneurysm. However, such stagnation forms a thrombus inside the aneurysm, that eventually can get resorbed.

We have discovered a method by which the desirable mechanical blockage of blood flow can be obtained with the addition of platelet adhesion to the embolic coils. This allows tissue to be able to grow, and the thrombus that forms, instead of being resorbed, has the ability to be organized into fibrous scar tissue. Such fibrous scar tissue achieves long term healing of the aneurysm in contrast to the use of embolic coils that can move around with the result that the formed thrombus may be resorbed.

The method that we have discovered is useful for occluding the vasculature of a patient. In addition to embolizing an aneurysm, the method of the present invention may also be used for embolizing a vessel for vessel sacrifice; for reducing or blocking blood flow to an arterial-venous malformation or to a fistula; and for blocking blood flow to tumors.

It is, therefore, an object of the present invention to provide a novel method for occluding the vasculature of a patient using implanted embolic coils in which there is improved platelet adhesion to the coils.

A further object of the present invention to provide a novel method for treating an aneurysm of a patient using implanted embolic coils in which there is improved platelet adhesion to the coils.

Another object of the present invention is to provide a novel method for treating an aneurysm of a patient using embolic coils and enabling tissue formation to prevent the coils from moving around within the aneurysm.

A further object of the present invention is to provide a novel embolic coil that

is simple in construction and easy to manufacture.

A still further object of the present invention is to provide a novel embolic coil which provides improved platelet adhesion.

Other objects and advantages of the present invention will become apparent as the description proceeds.

SUMMARY OF THE INVENTION

In accordance with the present invention, a method is provided for occluding the vasculature of a patient. The method comprises the steps of providing a plurality of embolic coils having a textured surface. The plurality of embolic coils having a textured surface are introduced into the patient's vasculature. In this manner, the textured surface provides improved platelet adhesion compared to a non-textured surface, to promote clotting.

In the illustrative embodiment, the surface of the embolic coils are textured by abrasion or sandblasting. The embolic coil comprises a platinum-tungsten alloy wire and in a specific example, the embolic coils have a substantially uniform roughness comprising pockets having diameters of between about 0.125 microns and about 50 microns and depths between about 0.25 microns to 20 microns.

A more detailed explanation of the invention is provided in the following description and claims, and is illustrated in the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a view of an embolic coil constructed in accordance with the principles of the present invention.

Fig. 2 is a diagram of a patient's brain aneurysm having the coils of the present invention implanted therein.

Fig. 3 is a photomicrograph, enlarged 233x, showing a portion of an embolic coil with a smooth surface, prior to texturing.

Fig. 4 is a photomicrograph, enlarged 233x, showing a similar portion of an embolic coil as the Fig. 3 portion, but with texturing.

Fig. 5 is a photomicrograph, enlarged 3880x, showing a portion of an embolic coil with a smooth surface, prior to texturing.

Fig. 6 is a photomicrograph, enlarged 3880x, showing a similar portion of an embolic coil as the Fig. 5 portion, but with texturing.

DETAILED DESCRIPTION OF THE ILLUSTRATIVE EMBODIMENT

Referring to the drawings, in Fig. 1 there is shown an embolic coil constructed in accordance with the principles of the present invention. Embolic coil 10 is formed by winding a platinum-tungsten alloy wire into a helical configuration. In the illustrative embodiment, the diameter of the wire is generally in the range of about 0.0015 to 0.008 inches. The outside diameter of the coil 10 is preferably in the range of about 0.006 to 0.055 inches. The embolic coil 10 shown in Fig. 1 may be straight

or may take the form of various configurations, including the form of a helix, a random shape configuration, or a coil within a coil configuration.

The details of construction of an example embolic coil, although no limitation is intended, is disclosed in Diaz et al. U.S. Patent No. 6,063,100, issued May 16, 2000, the disclosure of which is incorporated herein by reference.

With the helical wound coil as illustrated in Fig. 1, the coil is provided with a seal plug 12 at its distal end and another seal plug 14 at its proximal end. Seal plugs 12 and 14 serve to prevent the flow of fluid through the lumen of the coil 10.

Although no limitation is intended, as a specific example coil 10 is formed of a platinum-tungsten alloy comprising 92% platinum and 8% tungsten. In accordance with the present invention, the outer surface of the coil is textured by abrasion or sandblasting. To this end, fifty-micron diameter alumina particles are used to texture the surface of the wire that is used to form the coils, prior to the formation of the helical coils. It has been found that the textured surface provides improved platelet adhesion thus promoting clotting and subsequent endothelialization.

Although no limitation is intended, as a specific example the texturization provides a uniform roughness comprising pockets having diameters of between about 0.125 microns and about 50 microns and depths of between about 0.25 microns and about 20 microns. The roughness is uniform throughout the coil except if the coil is used with a detachment system such as disclosed in Hieshima U.S. Patent No. 6,113,622 or Diaz et al. U.S. Patent No. 6,063,100, a proximal portion of the coil is

not textured in order for it to have a proper seal with a gripper so that it can be released easily.

Fig. 2 is a diagrammatic view of a patient's vessel 16 leading to an aneurysm 18 into which a number of embolic coils 10 have been introduced. The coils are introduced in a manner known in the art, by introducing a catheter into the vessel 16, then introducing a deployment device via the catheter to deliver the embolic coils, one by one, to the aneurysm 18.

SEM micrographs of the non-textured vs. textured coils are provided in Figs. 3-6. Referring to Fig. 3, a portion of a non-textured coil is shown in a micrograph having an enlargement of 233x. Fig. 4 shows a similar coil with a 233x enlargement, but with texture that has been provided by sandblasting as disclosed above. Fig. 5 is a greatly enlarged micrograph, having an enlargement of 3880x, of the coil sample of Fig. 3 and Fig. 6 is a greatly enlarged micrograph having an enlargement of 3880x, of the coil sample of Fig. 5.

Testing was conducted using radiolabeled platelets to evaluate an ex vivo aneurysm model. In the model, aneurysms treated with textured coils were compared to aneurysms treated with non-textured coils. The textured coils showed an increase in the platelet deposition of about fifty percent over the non-texture coils.

It can be seen that by using embolic coils that have been textured, there is superior platelet adhesion which promotes clotting and subsequent endothelialization. A texturing technique has been disclosed that is simple and does not require expensive

or elaborate equipment to modify the coils. In the illustrative embodiment the texturing technique does not require coating or ion implantation, thereby avoiding the importation of any new materials to the coil that would require new biocompatibility testing.

Although an illustrative embodiment of the invention has been shown and described, it is to be understood that various modifications and substitutions may be made by those skilled in the art without departing from the novel spirit and scope of the present invention.